K060889

Pentron Clinical Technologies, LLC

Advancing dentistry one innovation at a time.™

OCT 27 2006

6.0 510(K) SUMMARY

Pentron Clinical Technologies, LLC.
68 North Plains Industrial Road
Wallingford, CT 06492
Tel: 203-265-7397
Fax: 203-265-3074
Contact: Greg Moreau

Trade Name:	SE Epiphany Root Canal Sealant
Common Name:	Dental root canal sealant
Classification Name:	Dental Root Canal Sealant, 21CFR 872.3820, KIF

SE Epiphany Root Canal Sealant product performs the same intended function as its predicate device, First Fill (reference K011748). Both devices are intended for the permanent obturation of root canals of teeth in combination with root canal points.

The subject device is a self-etch methacrylate resin root canal sealant in a catalyst/base paste formulation. Due to its self-etching and adhering properties, SE Epiphany Root Canal Sealant does not require the use of an etchant, primer or adhesive to achieve its intended function. SE Epiphany Root Canal Sealant has been designed for dual cure capabilities.

Device composition is approximately 60-70% filler by weight with filler particle size values less than 2 microns. As with other resin products manufactured by Pentron Clinical Technologies, LLC., the predominant filler for SE Epiphany Root Canal Sealant is a barium boro-silicate glass. This filler type provides the subject device with the required strength and radiopacity features.

Product is supplied within automix dual barrel syringes for ease of dispensing directly into the restorative site.

A review for safety and effectiveness was performed and found not to have been affected.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 2006

Mr. Greg Moreau
Pentron Clinical Technologies
68-70 North Plains Industrial Road
Wallingford, Connecticut 06492

Re: K060889
Trade/Device Name: SE Epiphany Root Canal Sealant
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Post
Regulatory Class: II
Product Code: KIF
Dated: October 6, 2006
Received: October 10, 2006

Dear Mr. Moreau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5.0 INDICATION FOR USE STATEMENT

510(k) NUMBER (IF KNOWN): K060889

DEVICE NAME: SE Epiphany Root Canal Sealant

INDICATION FOR USE:

SE Epiphany Root Canal Sealant is intended for permanent obturation of root canals of teeth in combination with root canal points.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over –The-Counter-Use** ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Kim Hedley for HSR

of Anesthesiology, General Hospital,
Control, Dental Devices

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